REMARKS/ARGUMENTS

I. Amendment to the Specification

Paragraph [00101] is amended to clarify that the means for injecting is for that of a liquid composition from the cavity (of the reservoir) through the needle, to correct an obvious typographical error.

II. Amendment to the Claims

Claims 1-17 are in the application. Claims 1, 3, 9, 10, 16 and 17 are amended. Claims 12-15 are canceled without prejudice. New Claims 18 - 22 are added.

Claim 1 is amended to delete the term "painlessly" in the preamble; to provide that the diameter size of the needle of less than about 0.38 mm effects a painless insertion of the needle into the patient (support at paragraph [0079]); to provide that the reservoir for the vaccine is in liquid communication with the needle (support inherent in the claim itself); to provide a means for injecting a vaccine from the reservoir through the needle (support is provided in paragraphs [0098] and [00101] in the specification as originally filed); to provide that the separable base secures the device to the skin of a patient during the time that the device self-administers the injection of the vaccine to the patient (support is provided in paragraphs [00113] and [00126] in the specification as originally filed); and to provide a base separation means for selectively separating the separable base from the device while the separable base is secured to the skin (support is provided in paragraph [00102] in the specification and in Figures 27 and 28 as originally filed).

Claim 3 is amended to provide that the separable base comprises an adhesive flap extending from a periphery of the separable base, and to delete the redundant feature of the flap providing securement of the separable base to the skin of the patient.

Claim 9 is amended to better present the feature of the claim.

Claim 10 is amended to better present the feature of the claim.

Claim 16 is amended to better present the feature of the claim.

Claim 17 is amended to provide that the constant volumetric flow rate of the vaccine from the reservoir through the needle effects a painless injection (support is found at paragraph [0079] in the specification as originally filed).

New Claim 18 depends from Claim 1 and provides that the injection device further comprises a means for retracting the injection needle which retracts the injection end of the needle from its extended position to a position within the housing (support is provided in Claim 9 as originally filed, as well as in paragraph [00104] in the specification and in Figure 27 as originally filed).

New Claim 19 depends from Claim 18 and provides that the at least one engaging member cannot be biased to its second position unless the needle is at its housing position, which prevents the injection end of the needle from extending beyond the base portion of the housing when the separable base is removed from the housing (support is provided in paragraph [00104] in the specification as originally filed).

New independent Claim 20 provides an injection device for self-administering vaccine injections to a patient, that is substantively identical to Claim 1 as originally filed: further providing that the reservoir for the vaccine is in liquid communication with the needle (support inherent in the claim itself); further providing a means for injecting a vaccine from the reservoir through the needle (support is provided in paragraphs [0098] and [00101] in the specification as originally filed); further providing that the separable base secures the device to the skin of a patient during the time that the device self-administers the injection of the vaccine to the patient (support is provided in paragraphs [00113] and [00126] in the specification as originally filed); and providing a means for retracting the injection needle, which retracts the injection end of the needle from its extended position to a position within the housing (support is provided in Claim 9 as originally filed).

New Claim 21 depends from Claim 20 and provides that the retracting means allows separation of the separable base from the separable base portion of the housing after the needle retraction means has biased the needle to retract to its housing position (support is provided in paragraph [00104] in the specification as originally filed).

New Claim 22 depends from Claim 20 and further provides a base separation means for selectively separating the separable base from the device while the separable base is secured to

the skin (support is provided in paragraph [00102] in the specification and in Figures 27 and 28 as originally filed).

No new claims fees are believed due, and all claim amendments are supported by the originally-filed specification as noted.

Rejections under 35 USC §103(a)

Claims 1-11, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McConnell-Montalvo (US 6939330) in view of Woehr et al. (US 20030144627) and Hunn et al (US 20040158207).

Applicants, without acquiescing whatsoever to the rejection or its bases, which were specifically traversed by Applicants in the last response, nonetheless request reconsideration and withdrawal of the rejection in view of the claim amendments made and the remarks that follow.

Claim 1 is amended, in part, to provide that the separable base comprises an adhesive that secures the device to the skin of a patient during the time that the device self-administers the injection to the patient. The specification provides at paragraph [0056] that the "self-administering" device holds itself in a position attached to the skin of a patient by a securement means, without requiring a medical technician, the patient, or other person, to hold the device, during the time that an injectable liquid composition contained within the device is injected into the patient through the injection needle.

The rejection of the combination of McConnell-Montalvo, Woehr et al, and Hunn et al fails to establish a *prima facie* obviousness rejection over the claims as amended.

The rejection states that the recitation of "self-administering" was given no patentable weight since it occurred in the preamble. The claim as amended provides that the separable base includes this feature. The rejection also stated that "any apparatus with a needle, if inserted at an injection site, is technically held in place as defined, since if released it would stay in place on the subject, and it must instead by manually removed by the person administering the injection" (page 9 of the Action mailed August 19, 2009). Applicants traverse. Official notice has been taken of a fact in support of the rejection that is not well known or is not of common knowledge in the art capable of instant and unquestionable demonstration as being well known. In particular, while it may be possible that an apparatus with a needle that is inserted and released

might stay in place, it is not common knowledge or well known whatsoever that such apparatus can continue injecting the vaccine or medicament into the patient through the injection needle if it has been released by the person administering the vaccine.

It is also noted that the claim as amended provides that the separable base, not the needle itself, secures the device to the skin of the patient. Neither McConnell-Montalvo et al nor Woehr et al describe a device that provides a base, separable or otherwise, that can hold itself in position attached to the skin of a patient without requiring someone to hold the device during the injection of the vaccine through the injection needle. On the contrary, the devices of McConnell-Montalvo et al and Woehr et al make no disclosure or suggestion that the device itself is to be attached to the skin during the injection of the vaccine. Quite the contrary, a person of ordinary skill would clearly understand that McConnell-Montalvo et al and Woehr et al provide a device that is held by hand up to or against the skin for only so long as it takes the user to insert the needle and plunge the contents of the reservoir through the needle.

Applicants therefore, regarding Claims 1-5 and 16, traverse the assertion (page 4 item 6) that "it would be obvious to one having ordinary skill in the art at the time the invention was made to modify the McConnell-Montalvo et al. apparatus such that it comprises an adhesive on a skin-facing surface thereof, an adhesive flap extending from a periphery of the separable base, the flap having an adhesive on a skin-facing surface thereof, whereby the flap provides securement of the separable base to the skin of the patient, as taught by Hunn et al, for the purpose of holding the apparatus in place at an injection site." The basis of the assertion needs correction. Hunn et al at paragraph 0064 is describing Figure 1, not Figure 9 as asserted. Rather, Figure 9 and associated Figures 10 and 11, are described at paragraphs 0073-0076. Figures 9-11 and the associated description describe a needle 8 that is used to insert a cannula 3, through which a liquid is infused into the surrounding tissue. With all due respect, vaccine injection and liquid infusion are distinct functions and fields of art, and the teachings of these references are quite diverse: the needle of Hunn et al is used only to insert the cannula; neither Hunn et al nor McConnell-Montalvo et al describe any flow rate, but it can be reasonably concluded that each operates in quite diverse flow rate regimes. While it may be alleged to modify the McConnell-Montalvo et al. apparatus with an adhesive flap extending from a periphery of the alleged base, to secure the apparatus to the skin, the person of ordinary skill would have no reason whatsoever to do so; in fact, Hunn et al would suggest that the alleged base would be affixed to the skin of

the person for an unspecified though extended period of time, while the person of ordinary skill in the art would expect the apparatus of McConnell-Montalvo et al to be in contact with the skin for a period of time measured in seconds. The means of use and function of the two devices are obviously so different, that a person of ordinary skill should recognize that modifying the one with features of the other would interfere with the basic principle of operating of the one. Therefore, it would not be obvious to a person of ordinary skill why one would modify the apparatus of McConnell-Montalvo et al with the alleged base and adhesive flaps of Hunn et al.

The rejection has asserted that the McConnell-Montalvo apparatus is capable of administering a painless injection, especially to a subject or injection location with a high pain threshold. Applicants traverse this assertion. An assertion that, as a fact, some subjects or injection locations have a high pain threshold, requires some reference in support, since it is not the kind of fact that can be readily accepted as general knowledge. Furthermore, even if, for argument sake, one can identify a patient type or an injection location that is more tolerant of pain, a person or ordinary skill in the art would understand that the McConnell-Montalvo apparatus is routinely used to deliver vaccine injection to ordinary patient populations and injection locations where high pain as a result of use of the apparatus is the norm, not the rare exception.

Regarding Claim 17, the rejection states that it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver medicament within the claimed range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involved only routine skill in the art, citing *In re Aller*.

Applicants traverse this assertion. None of McConnell-Montalvo, Woehr et al, and Hunn et al make any disclosure of a flow rate *per se*. None of McConnell-Montalvo, Woehr et al, and Hunn et al make any disclosure of a flow that can effect a painless intermuscular injection of a vaccine. At a minimum, the assertion requires that the combination of references expressly or inherently teach all features of Applicants' claim. Since the claimed ranges does not "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness does not exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). Applicants respectfully note that *In re Aller* relates to optimization of a range within the conditions taught by the prior art, not to

establishing the obviousness of a range out of a general body of knowledge.

Prosecution of Related Patent Applications

Applicants wish to bring to the Examiner's attention the examination status of related patent applications commonly assigned to the assignee of the instant application:

i) **US Appln. 10/605,187** (Attorney docket CHM-005M), stands allowed. Applicant has presented on October 12, 2009 an RCE and a preliminary amendment in order to present certain new claims for the Examiner's consideration for allowance that were canceled by Applicant in a prior response, and to present additional new claims based upon the previously allowed claims.

ii) **US Appln. 10/597,991** (Attorney docket CHM-021M), an early response was filed on October 5, 2009 to final rejection.

Conclusion

Applicants believe a complete response to the office action has been provided, and that the present invention as claimed clearly distinguishes the teachings of the prior art of record. Applicants request a prompt allowance of all claims.

Respectfully submitted,

For: Eric James WALL et al.

By: _____

Daniel F. Nesbitt
Attorney for Applicants
Registration No. 33,746
(513) 229-0383
Customer Number 38155

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